

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

MITSUBISHI CHEMICAL CORPORATION,
 MITSUBISHI TANABE PHARMA
 CORPORATION,
 ENCYSIVE PHARMACEUTICALS INC.,
 GLAXO GROUP LIMITED,
 SMITHKLINE BEECHAM PLC, AND
 SMITHKLINEBEECHAM PLC CORP. D/B/A
 GLAXOSMITHKLINE,

Plaintiffs,

v.

BARR LABORATORIES, INC. AND
 PLIVA-HRVATSKA D.O.O,

Defendants.

Civil Action No. 1:07-CV-11614-JGK

Electronically Filed

ANSWER TO COUNTERCLAIM

Plaintiffs and counterclaim defendants, Mitsubishi Chemical Corporation, Mitsubishi
 Tanabe Pharma Corporation, Encysive Pharmaceuticals Inc., Glaxo Group Limited, SmithKline
 Beecham plc, and SmithKline Beecham Corp. d/b/a GlaxoSmithKline, by their undersigned
 counsel, hereby answer the Counterclaim of defendants and counterclaim plaintiffs Barr
 Laboratories, Inc., and Pliva-Hrvatska, d.o.o. as follows:

Jurisdiction and Venue

1. The allegations of paragraph 1 of the counterclaim state conclusions of law rather than allegations of fact to which a response is required.

2. The allegations of paragraph 2 of the counterclaim are admitted, insofar as counterclaim plaintiffs purported to challenge the validity of the '052 Patent in ANDA No. 79-238. The remaining allegations of paragraph 2 of the counterclaim are denied.

The Parties

3. The allegations of paragraph 3 of the counterclaim are admitted, upon information and belief.

4. The allegations of paragraph 4 of the counterclaim are admitted, upon information and belief.

5. The allegations of paragraph 5 of the counterclaim are admitted.

6. The allegations of paragraph 6 of the counterclaim are admitted.

7. The allegations of paragraph 7 of the counterclaim are admitted.

8. The allegations of paragraph 8 of the counterclaim are admitted.

The Abbreviated New Drug Application

9. In response to paragraph 9 of the counterclaim, counterclaim defendants admit that ANDA No. 79-238 was filed and that it contained a document purporting to be a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(iv), but deny the sufficiency thereof.

COUNT I

Declaratory Judgment of Invalidity of The '052 Patent

10. The allegations of paragraph 10 of the counterclaim are denied.

**AFFIRMATIVE DEFENSES
FIRST AFFIRMATIVE DEFENSE**

Counterclaim plaintiffs fail to state a claim against counterclaim defendants upon which relief can be granted.

PRAYER FOR RELIEF

WHEREFORE, plaintiffs and counterclaim defendants Mitsubishi Chemical Corporation, Mitsubishi Tanabe Pharma Corporation, Encysive Pharmaceuticals Inc., Glaxo Group Limited, SmithKline Beecham plc, and SmithKline Beecham Corp. d/b/a GlaxoSmithKline respectfully request that the Court enter judgment against defendants and counterclaim plaintiffs Barr Laboratories, Inc., and Pliva-Hrvatska, d.o.o. as follows:

- (a) a judgment that making, using, selling, offering to sell and/or importing defendants' and counterclaim plaintiffs' drug product for which they seek FDA approval will infringe, induce infringement of, and/or contributorily infringe at least one claim of the '052 Patent;
- (b) a declaratory judgment pursuant to 28 U.S.C. § 2201 et seq. that making, using, selling, offering to sell and/or importing defendants' and counterclaim plaintiffs' drug product for which they seek FDA approval will infringe, induce infringement of, and/or contributorily infringe at least one claim of the '052 Patent;
- (c) a judgment and order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval for defendants and counterclaim plaintiffs to commercially make, use, sell, offer to sell or import defendants' and counterclaim plaintiffs' drug product for which they seek FDA approval be no earlier than the date following the expiration date of the '052 Patent;
- (d) a permanent injunction restraining and enjoining against any infringement, inducement of infringement, or contributory infringement by defendants and counterclaim plaintiffs, their officers, agents, attorneys, and employees and those

acting in privity or concert with all or any of them, of the '052 Patent through the commercial manufacture, use, sale, offer for sale or importation into the United States of Defendants' drug product for which it seeks FDA approval;

- (e) A declaratory judgment that the '052 Patent is valid;
- (f) Judgment that defendants and counterclaim plaintiffs take nothing by their counterclaim against the plaintiffs and counterclaim defendants and that the counterclaim be dismissed with prejudice;
- (g) Declaring that this action is exceptional pursuant to 35 U.S.C. § 285, and awarding the plaintiffs and counterclaim defendants their costs and reasonable attorneys' fees incurred in connection with this action; and
- (h) Granting such other and further relief as this Court deems just and proper.

Dated: April 24, 2008

/s/Kathleen B. Carr

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) on April 24, 2008, and if there are non-registered participants, the motion will be sent by first-class mail.

/s/ Kathleen B. Carr

Kathleen B. Carr